

REMARKS

Claims 217-242 were presented for examination in the present application and remain pending for consideration upon entry of the instant amendment.

Claims 217-242 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 78 and 217-306 of copending Applicant No. 10/888,242. Applicants will respond by way of terminal disclaimer, amendment, or other suitable response when the provisional rejection has been made non-provisional.

Claims 217-220, 222-239, 241, and 242 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,327,076 ("Puglia") in view of U.S. Patent No. 4,163,777 ("Mitra"). Claims 221 and 240 were rejected under 35 U.S.C. 103(a) as being unpatentable over Puglia in view of Mitra and U.S. Patent No. 6,197,329 ("Hermelin").

Claim 217 recites "A pharmaceutical composition, comprising in admixture: an alginic acid or a salt thereof; a water-soluble carbonate radical precursor; a calcium salt; and a first bulk sweetener, wherein the composition is in powder form (emphasis added)".

Puglia discloses a compressed soft chewable tablet which may contain an antacid, has good flexibility, is breakage resistant and disintegrates immediately upon chewing. The tablet is formed of particles of antacid which are isolated from other ingredients of the tablet. The tablet also includes additional amounts of tablet bonders, flavors and other tableting aids.

First, as noted above, claim 217 requires a pharmaceutical in powder form. The composition of Puglia is a tablet. There is nothing in Puglia to disclose or suggest a powder form. Moreover, none of the cited art discloses the pharmaceutical composition in powder form as required by claim 217. For at least these reasons, claim 217 is patentable over the cited art.

In addition, the Office Action acknowledges that "Puglia does not expressly teach a water soluble carbonate radical precursor". See, page 4, line 3.

However, the Office Action asserts that "It would have been obvious to one of ordinary skill in the art... to make a composition comprising alginic acid, bulk sweetener and calcium carbonate, as suggested by Puglia, combine it with the antacid delivery form including a water soluble carbonate radical precursor such as sodium bicarbonate, as suggested by Mitra, and produce the instant invention". See, page 4, line 19 - page 5, line 2.

The Office Action asserts that "One of ordinary skill in the art would do this because the water soluble carbonate radical precursors... are known to be used in antacid formulation, as evidenced by the teaching of Mitra". See, page 5, lines 3 - 5.

Applicants respectfully submit that the Office Action has used an improper standard in arriving at the rejections of the above claims under section 103, based on improper hindsight which fails to consider the totality of Applicants' invention and the totality of the cited references. More specifically, the Office Action has used Applicants' disclosure to select portions of the

cited references to allegedly arrive at Applicants' invention.

There is simply no reason why one of ordinary skill in the art practicing the invention of Puglia would modify the Puglia tablets so as to include the water soluble carbonate radical precursors, such as sodium bicarbonate.

In the present invention, the water soluble carbonate radical precursor is involved in the formation of a raft. The raft forms a physical barrier to acid refluxing into the esophagus. The raft is a matrix of alginate salts. The salt forms result from the interaction between the alginic acid and the salt source, such as calcium carbonate, sodium bicarbonate, and/or potassium bicarbonate. Further, the raft is made buoyant by the bicarbonate salt interacting with stomach acid to generate carbon dioxide gas or bubbles. The bubbles are entrapped in the matrix and allow the raft to float on top of the gastric contents. Calcium ions are also believe to serve to cross-link the precipitated alginic acid molecules and, thus, strengthen the gel matrix. See, page 7, lines 10 - 28.

Puglia discloses that "[I]n accordance with the present invention, a unique compressed chewable tablet is provided which has excellent hardness and flexibility, is breakage and chip resistant and yet may be easily chewed and quickly disintegrated and dissolved in the mouth". See, col. 2, lines 47-51.

While the use of water soluble carbonate radical precursors used in conjunction with antacid formulations may or may not have been known in the prior art, there is simply no reason to modify the tablets of Puglia as asserted. The addition of a water soluble carbonate radical precursor does nothing to further the objective of

Puglia providing a tablet that has excellent hardness and flexibility, is break and chip resistant, yet can be easily chewed and quickly disintegrated. Why would one of ordinary skill add an ingredient that does nothing to further the objective? To do so would needlessly increase the costs of producing the tablet. Furthermore, it would likely alter the desired properties of the tablet, all for no apparent reason. Applicants respectfully submit that there is no logical reason to modify the tablets of Puglia as asserted in the Office Action. The Office Action's combination is merely based on hindsight based on disclosure of the present application. Had it not been for that which is learned from the present application, there is no reason to combine the references as asserted.

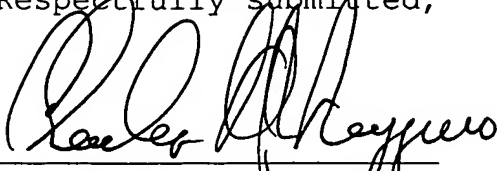
Therefore, Applicants respectfully submit that one of ordinary skill in the art would not combine Puglia and Mitra as asserted. Accordingly, claim 217 is in condition for allowance. Claims 218 through 242 depend from independent claim 217 and are in condition for allowance for at least the reasons set forth above with regard to claim 217. Reconsideration and withdrawal of the rejections to claims 217 through 242 are respectfully requested.

In view of the above, it is respectfully submitted that the present application is in condition for allowance. Such action is solicited.

If for any reason the Examiner feels that consultation with Applicants' attorney would be helpful in the advancement of the prosecution, the Examiner is invited to call the telephone number below.

Respectfully submitted,

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